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<p>(21) International Application Number: PCT/GB92/01722 (22) International Filing Date: 18 September 1992 (18.09.92) (30) Priority data: 917479 19 September 1991 (19.09.91) ZA (71) Applicant (for all designated States except US): SURGIC-RAFT LIMITED [GB/GB]; Fishing Line Road, Redditch, Worcestershire B97 6HF (GB). (72) Inventor; and (75) Inventor/Applicant (for US only): HOFMEYR, George, Justus [ZA/ZA]; Holding 32, Chantwell, Transvaal Province (ZA). (74) Agents: PEARCE, Anthony, Richmond et al.; Marks & Clerk, Alpha Tower, Suffolk Street Queensway, Birmingham B1 1TT (GB).</p>		<p>(81) Designated States: AU, CA, JP, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, SE). Published <i>With international search report.</i></p>
<p>(54) Title: A DEVICE FOR USE IN MONITORING ELECTRIC SIGNALS GENERATED BY THE HUMAN BODY</p> <div data-bbox="467 1123 1198 1690"> </div> <p>(57) Abstract</p> <p>The device for attachment to the skin of a fetus has a suction cup (12) with an electrode (14) across its mouth. The electrode (14) is formed of a flat plate having a multiplicity of apertures (16) therethrough. The apertures (16) are distributed over the whole of the cross-sectional area of the plate. The suction cup (12) is connected via a tube (22) with a conventional syringe (20) which can be retained in a piston-withdrawn position by means of an external retainer (36). With mouth of the suction cup (12) against the fetal skin, operation of the syringe (20) by withdrawing the piston (34) thereof causes a reduced pressure to be applied via the apertures in the electrode to draw the skin into electrical contact with the electrode (14).</p>		

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A DEVICE FOR USE IN MONITORING ELECTRIC SIGNALS
GENERATED BY THE HUMAN BODY

This invention relates to a device attachable to the body of a human subject, for use in monitoring electrical signals, eg electric currents, generated by the human body, and is more particularly concerned with fetal monitoring.

Many fetal electrocardiograph (ECG) electrodes currently in use to obtain fetal heart rate recordings during labour, employ single or double curved needles which penetrate the fetal skin on the scalp to obtain purchase and maintain electrical contact. There have been reports of neonatal scalp infections following the use of penetrating (or invasive) scalp electrodes during labour, even resulting in neonatal deaths. For example, US-A-4299232 discloses an invasive fetal scalp electrode device.

It has also been previously proposed to provide a non-invasive monitoring device for attachment to the fetal scalp electrode device in which a sensor is held in position against the fetal scalp by suction. For example, US-A-4537197 discloses a device where the ends of optical fibres leading respectively to a light source and a light sensor are exposed within a suction cup which is connected via a tube with a syringe which is operable to withdraw air from the suction cup. GB-A-1260919, WO 91/15996 and WO 92/04864 disclose fetal scalp electrode devices where the electrode is provided within a cup-shaped body in which a reduced pressure is applied to draw the fetal skin into engagement with the electrode in use. In GB-A-1260919 and WO 91/15996, the electrode is disposed centrally within the cup-shaped body and the skin is drawn against the surface of the electrode by reduced pressure which is applied via an annular space

defined between the mouth of the cup-shaped body and the outer periphery of the electrode. In WO 92/04864, the electrode is annular and is provided around and just inside the mouth of cup-shaped body. The fetal skin is drawn into the cup-shaped body and into engagement with the annular electrode by means of a reduced pressure which is applied to the cup-shaped body via a central apertured insert which does not form the electrode but which also serves to prevent undue stretching of the fetal tissue.

DE-U-8907755 discloses a monitoring device which is held against the body of a patient by suction but which is not designed for fetal scalp attachment. In such device, a cup-shaped body has a side connection for attachment to a source of reduced pressure, and an internal ball valve arrangement actuatable by a lug integral with an elastic top wall of the body. A metal electrode in the form of a stepped plate is provided across the interior of the body. A ring of apertures is provided in a portion of the electrode plate which is adjacent the periphery of the body and which is stepped back from an unapertured annular mid-region of the electrode plate. A sponge pad is disposed in the body and rests against such mid-region. In use, the sealing mouth of the body is pressed against the body of the patient and the elastic top wall of the body depressed to cause the lug to open the ball valve which is maintained open. Reduced pressure is applied via the ring of apertures and through the sponge pad. The suction serves to draw the skin of the patient against the sponge pad which is soaked with liquid to improve electrical contact between the electrode and the skin of the patient.

According to the invention, there is provided a device for use in monitoring fetal signals, eg electric currents generated by the heartbeats or brain of a fetus,

said device comprising

a hollow body having a mouth which is adapted to be sealed with the skin of a fetus being monitored in use;

an electrode mounted within said hollow body for sensing said fetal signals and connected in use to a monitoring apparatus; and

connection means for enabling reduced pressure to be applied to the hollow body to enable the electrode to be brought into a signal monitoring position relative to the fetus;

characterised in that the electrode comprises an electrically conductive electrode plate having a multiplicity of apertures therethrough distributed over its surface area and through which apertures the reduced pressure within the hollow body is applied in use to the fetal skin.

Preferably, the apertures are distributed over a majority of the surface area of the electrode plate.

It is preferred for the apertures to be provided over a region of the electrode plate against which the fetal skin is destined to be engaged in use by the reduced pressure applied to the fetal skin through the apertures.

The device according to the invention can conveniently be attached to the scalp of a fetus while its mother is in labour.

The apertures may comprise a multiplicity of holes drilled, punched or otherwise formed therethrough. Such holes are preferably distributed over substantially the whole of the cross-sectional area of the plate. Alternatively, the electrode plate may comprise a wire mesh, preferably a mesh formed of wires of circular

cross-section. The use of such a mesh can be advantageous in mitigating the risk of damage to the fetal skin when drawn against the plate.

The apertured plate is preferably planar, but it is within the scope of the invention to for the plate to be non-planar eg of convex or shallow conical shape, or for the plate to have one or more projections, ribs, ridges or other protuberances eg an annular rib or ribs on the exposed surface of the plate if it is desired to promote a localised, slightly increased contact pressure between fetal skin and plate in order to accelerate the generation of a detectable signal upon fitting.

The use of an electrode of the type defined in the device of the present invention can enable effective suction of the fetal skin against a substantial area, preferably the whole area, of the electrode without the risk applying excessive reduced pressure to a very localised area of the fetal skin, thereby enabling fetal skin damage to be mitigated whilst at the same time promoting effective electrical contact between the skin and the electrode.

In a preferred arrangement, the fetal skin is drawn into direct physical contact with the apertured plate. It is, however, within the scope of the present invention to provide a thin permeable pad or the like over the otherwise exposed surface of the plate in order to reduce further the risk of fetal skin damage. In such a case, such pad will normally be saturated with a physiologically acceptable, electrically conductive liquid or gel, such as isotonic saline or a proprietary electrode gel, to promote effective electrical contact between the fetal skin and the apertured plate.

The connection means of the device of the present

invention is preferably connected to the side of the hollow body to facilitate passage of the hollow body of the device to a position alongside the fetal presenting part.

The connection means may be adapted for connection via flexible tubing with a reduced pressure source such as is commonly provided in hospitals. Alternatively, the device may further include suction means remote from the hollow body and in fluid communication with the connection means. Such suction means may comprise a receptacle and means for manually varying the volume of the receptacle to enable a reduced pressure to be applied to the connection means, and thereby to the hollow body, from a location remote from the hollow body of the device.

Preferably, the suction means comprises a conventional syringe comprising a cylinder with a nozzle and a piston which is reciprocally displaceable within the cylinder to vary the internal volume of the cylinder. The syringe may be fitted with a retainer for retaining the piston in a withdrawn position, ie in a position in which the volume of the cylinder is relatively great.

Preferably, the retainer is adapted to be fitted externally of the syringe and may comprise first and second engaging formations which are spaced apart at a fixed distance from each other to permit simultaneous engagement of the first and second engaging formations with the cylinder and the piston respectively when the piston is in its withdrawn position.

The fixed distance at which the first and second engaging formations are spaced apart from each other may approximate to the length of the piston, the first and second engaging formations being adapted to engage

respective lip formations at the end of the cylinder remote from the nozzle and at the free end of the piston respectively. Further engaging formation may be provided on the retainer to allow varying suction settings to be applied.

In one preferred arrangement, the hollow body, the connection means and the suction means are completely filled with a suitable liquid, eg isotonic saline, so as to exclude air from the device and so improve the reduced pressure applied in use. An advantage of such an arrangement is that liquid drawn into the receptacle of the suction means may be flushed through the device whilst the hollow body is held against the fetal skin to wash substances such as mucus and vernix caseosa from the skin underlying the electrode plate and so improve electrical contact.

The invention is now described by way of the following non-limiting examples in which:

Fig. 1 is a three-dimensional view of a device according to the invention for use in monitoring electric currents generated by the heartbeats of a fetus, and connected to a suction means with a retainer according to the invention, shown in side elevation;

Fig. 2 is a section through the device of Figure 1;

Fig. 3 is a plan view of an alternative form of electrode plate forming part of the device; and

Fig. 4 is a section similar to Fig. 2 of a further embodiment.

In the drawings, reference numeral 10 generally indicates a device according to the invention for use in monitoring electric currents generated by the heartbeats of a fetus.

The device 10 includes a hollow body in the form of a suction cup 12 of silicone rubber or the like and having a mouth which sealingly embraces a sensor electrode 14 in the form of a metal disc having a plurality of apertures 16 through which the interior 18 of the suction cup 12 is in communication with the exterior. The apertures 16 are distributed over the whole of the exposed surface area of the electrode 14. In this embodiment, the diameter of the electrode 14 is 15 mm and there are nine apertures 16 therethrough, each having a diameter of 1.5 mm. In an alternative embodiment (not shown), there are 80 apertures, each having a diameter of 0.75 mm.

The suction cup 12 is connectable to a syringe 20 via a flexible tube 22 which extends laterally from the interior 18 of the cup 12 to which it is sealingly fastened.

A reference electrode 24 is fastened to the back surface of the cup 12.

The sensor electrode 14 and the reference electrode 24 can be linked to a conventional cardiocograph via separate, electrically conductive wires 26, 28 respectively.

The syringe 20 is a conventional one, comprising a cylinder 30 with a nozzle 32 at one end and a piston 34 reciprocally displaceable within the cylinder 30 between a first position in which it is at or adjacent the nozzle 32 and occupies a major proportion of the internal volume of the cylinder 30, and a second, withdrawn position which is shown in Figure 1, which is remote from the nozzle 32 and occupies only a small proportion of the volume of the cylinder 30.

Reference numeral 36 generally indicates a retainer for retaining the piston 34 in its second, withdrawn position.

The retainer 36 has a stem 38 terminating in first and second engaging formations 40, 42 respectively which thus are spaced apart a fixed distance which is determined by the length of the stem 38, and which formations 40, 42 are engageable with lip formations 44, 46 at the end 48 of the cylinder 30 remote from the nozzle 32 and at the free end 50 of the piston 34 respectively. The formations 40, 42 define recesses 40.1, 42.1 in which parts of the respective lip formations 44, 46 are receivable. The retainer 36 is of a plastics material and the relative dimensions of the lip formations 44, 46 and recesses 40.1 and 42.1 permit the engaging formations 40, 42 to be clipped over portions of the lip formations 44, 46, thereby to maintain the operative position of the retainer 36 on the syringe 20.

A method of using the device described above is hereinafter described.

The nozzle 32 of the syringe 20 is sealingly connected to the suction cup 12 via the flexible tube 22 while the piston 34 occupies its first position in the cylinder 30 adjacent the nozzle 32. The whole device is filled with liquid, in this embodiment isotonic saline. The device 10 is placed and held against the presenting part of the fetus, usually the fetal scalp, and the piston 34 of the syringe is depressed to flush the liquid through the suction cup 12 and the apertures 16 to wash substances such as mucus and vernix caseosa from the fetal skin underlying the electrode 14. With the suction cup 12 still held against the fetal skin, the piston 34 is displaced to its second, withdrawn position shown in

Figure 1. A partial vacuum is thus created within the cylinder 30 and causes suction to be applied in the region of the mouth of the suction cup 12, thereby producing sealing of the periphery of the mouth of the cup 12 to the fetal skin. At the same time the fetal skin is drawn into close contact with the electrode 14 over the whole of the exposed surface thereof, thereby to ensure that an effective electrical contact is maintained between the two without applying undue pressure to the fetal skin.

The retainer 36 is clipped in its operative position to the syringe 20 to resist displacement of the piston 34 towards the nozzle 32 and thereby to maintain the partial vacuum within the cylinder 30 and hence the application of suction at the electrode 14.

The sensor and reference electrodes 14, 24 are connected to a conventional electrocardiograph which produces a record of the electric currents generated by the fetal heartbeats.

In the embodiment of Fig. 3, the electrode 14 is constituted by a fine mesh plate formed by woven wires 15 of circular cross-section, and the apertures 16 are defined by the interstices of the mesh. In the embodiment of Fig. 4, the electrode 14 is constituted by a plate which is of shallow conical form with a radiussed outwardly presented apex. The apertures 16 are distributed over the whole of the exposed surface of the electrode 14 except for the apex. Such an arrangement accelerates the generation of a detectable signal upon fitting of the device because the slightly increased initial contact pressure at the apex and the shape of the latter promotes penetration of the electrode 14 through mucus and/or vernix caseosa on the fetal skin under the electrode.

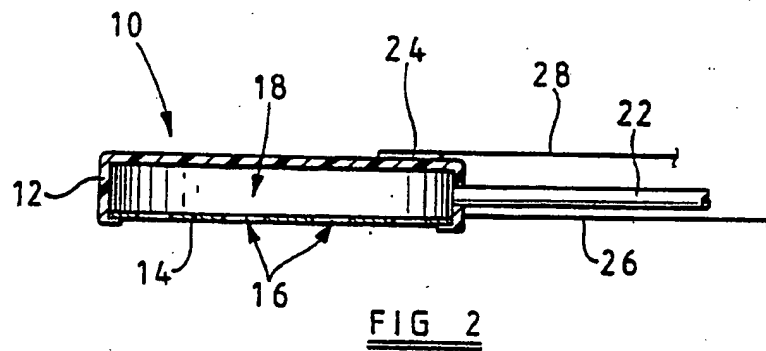
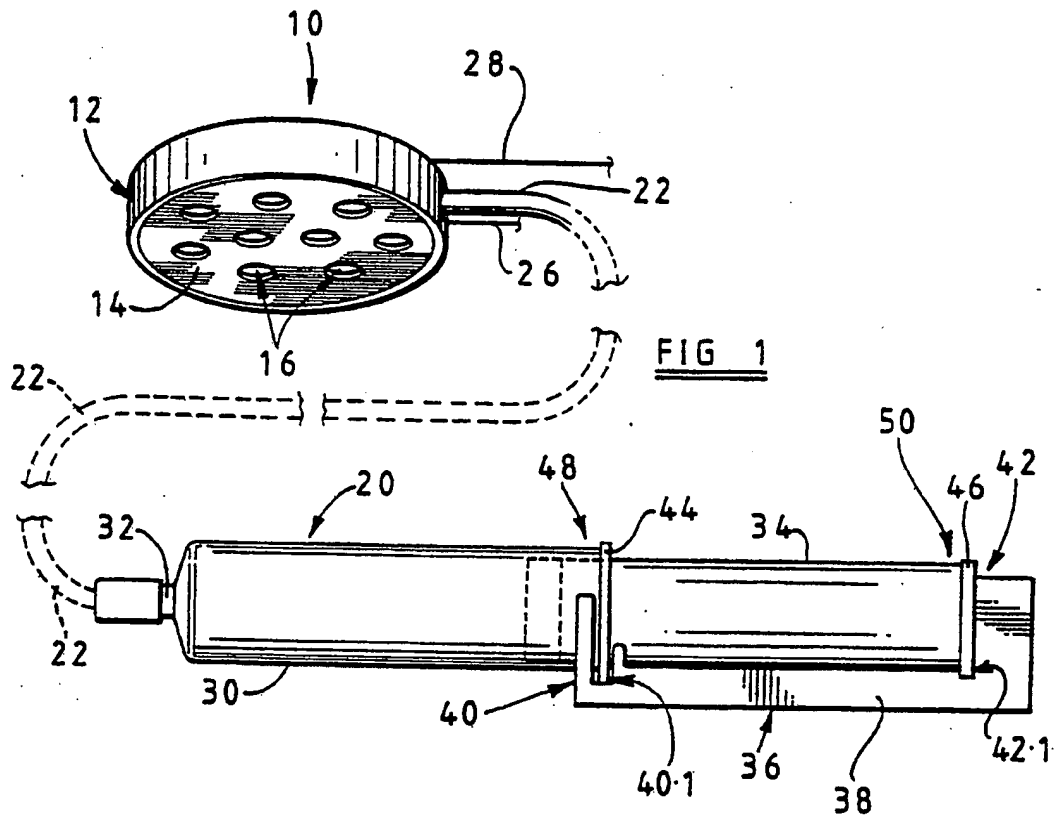
CLAIMS

1. A device for use in monitoring fetal signals, comprising
a hollow body (12) having a mouth which is adapted to be sealed with the skin of a fetus being monitored in use;
an electrode (14) mounted within said hollow body (12) for sensing said fetal signals and connected in use to a monitoring apparatus; and
connection means (22) for enabling reduced pressure to be applied to the hollow body (12) to enable the electrode (14) to be brought into a signal monitoring position relative to the fetus;
characterised in that the electrode comprises an electrically conductive electrode plate (14) having a multiplicity of apertures (16) therethrough distributed over its surface area and through which apertures (16) the reduced pressure within the hollow body (12) is applied in use to the fetal skin.
2. A device as claimed in claim 1, wherein the apertures (16) are distributed over a majority of the surface area of the electrode plate (14).
3. A device as claimed in claim 1 or 2, wherein the apertures (16) are provided over a region of the electrode plate (14) against which the fetal skin is destined to be engaged in use by the reduced pressure applied to the fetal skin through the apertures (16).
4. A device as claimed in any preceding claim, wherein the apertures (16) comprise a multiplicity of holes formed through the electrode plate (14).
5. A device as claimed in claim 4, wherein the holes (16) are distributed over substantially the whole of the

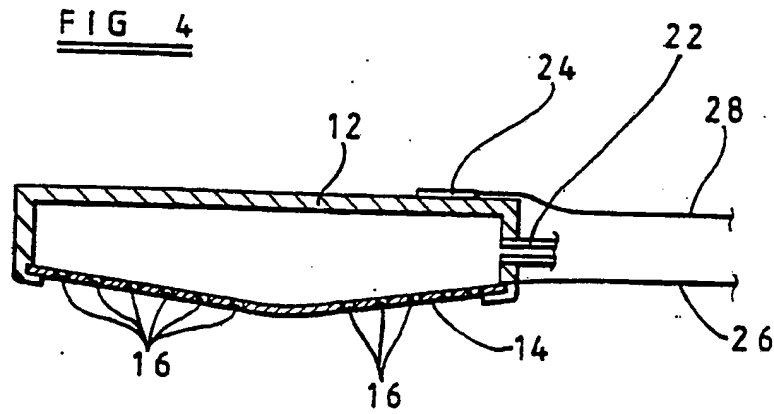
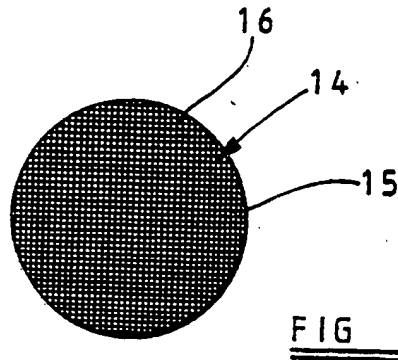
cross-sectional area of the electrode plate (14).

6. A device as claimed in claim 1, 2 or 3, wherein the electrode plate (14) comprises a wire mesh.
7. A device as claimed in claim 6, wherein the mesh is formed of wires (15) of circular cross-section, and the apertures (16) are defined by the interstices of the mesh.
8. A device as claimed in any preceding claim, wherein the electrode plate (14) is planar.
9. A device as claimed in any preceding claim, further including suction means (20) in, or adapted to be in, fluid communication with the connection means (22)
10. A device as claimed in claim 9, wherein the suction means (20) comprises a syringe comprising a cylinder (30) with a nozzle (32) and a piston (34) which is reciprocally displaceable within the cylinder (30) to vary the internal volume of the cylinder (30), and wherein the device further includes a retainer (36) for retaining the piston (34) in a withdrawn position.
11. A device as claimed in claim 10, wherein the retainer (36) is adapted to be fitted externally of the syringe (30)
12. A device as claimed in claim 11, wherein the retainer (36) comprises first and second engaging formations (40,42) which are spaced apart at a fixed distance from each other to permit simultaneous engagement of the first and second engaging formations (40,42) with the cylinder (30) and the piston (34) respectively when the piston (34) is in its withdrawn position.

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 92/01722

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl. 5 A61B5/0448		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
Int.Cl. 5	A61B ; A61M	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	US,A,3 505 993 (LEWES ET AL.) 14 April 1970 see column 4, line 6 - line 47; figure 4 ---	1-5,8,9
X	US,A,1 585 104 (MONTGOMERY) 18 May 1926 see page 1, line 87 - page 3, line 72; figures ---	1-3,5,6, 8,9
X	DE,C,332 212 (RESENER) 2 March 1919 see the whole document ---	1-5,8,9
A	US,A,4 537 197 (HULKA) 27 August 1985 cited in the application see the whole document ---	1,3,9,10
-/--		
<p>¹⁰ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"A" document member-of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
17 NOVEMBER 1992	02.12.92	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	CHEN A.H.	

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	US,A,3 669 111 (DUBNER) 13 June 1972 see column 2, line 35 - column 3, line 29; figures 2-4 -----	10-12

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

GB 9201722
SA 64670

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-3505993	14-04-70	GB-A- 1128329	
US-A-1585104		None	
DE-C-332212		None	
US-A-4537197	27-08-85	GB-A, B 2155618	25-09-85
US-A-3669111	13-06-72	None	